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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,480	11/20/2003	Yoshiya Gunji	US-102	9006

38108 7590 10/18/2005

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EXAMINER

ROBINSON, HOPE A

ART UNIT PAPER NUMBER

1656

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/716,480

Applicant(s)

GUNJI ET AL.

Examiner

Hope A. Robinson

Art Unit

1656

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 20 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 2-4, 6 and 7.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See the attached sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_

13. ☐ Other: \_\_\_\_\_.

  
**KATHLEEN M. KERR, PH.D.**  
**SUPERVISORY PATENT EXAMINER**

## **DETAILED ACTION**

### ***Application Status***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.
2. Applicant's response to the Office Action mailed May 23, 2005 on September 20, 2005, is acknowledged.

### ***Claim Disposition***

3. Claims 1 and 5 have been canceled. Claim 2 has been amended. Claims 2-4 and 6-9 are pending. Claims 2-4 and 6-7 are under examination.

### ***Priority***

4. As previously noted, the instant application is granted the benefit of priority for the foreign application 2002-336315 filed in Japan on November 20, 2002. No translation has been received; thus, the priority document cannot be used to pre-date any intervening prior art between the filing date of the instant application and the filing date of the foreign priority documents because said papers are not in English.

***Information Disclosure Statement***

5. As previously noted, the submitted copy of the referenced document Teizi *et al.* listed on the information disclosure statement (IDS) filed April 6, 2004 was not considered because it was incomplete. A complete copy of the referenced document Teizi *et al.* was received on February 15, 2005, and has been considered as noted by the Examiner's initials on the attached copy of the IDS.

***Compliance with the Sequence Rules***

6. As previously noted, the statement submitted on April 02, 2004 that affirms that the content of the sequence listing information in the CRF is identical to the paper copy of the sequence listing, and, where applicable, includes no new matter is unsigned. A signed statement regarding the sameness of the CRF and the paper copy of the sequence listing was received February 15, 2005; however the statement does not affirm that no new matter is included in the CRF. Therefore, the instant application fails to fully comply with the sequence rules. A signed statement regarding no new matter is required. It is noted that applicant on page 4 of the response indicates that a signed statement is herein provided, however, none was found.

***Withdrawn Claim Rejections 35 U.S.C. § 112***

7. The previous rejection of claims 2-4 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn by virtue of Applicant's amendment.

***Maintained Claim Rejections 35 U.S.C. § 112***

8. The previous rejection of claims 2-4 and 6-7 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained. Applicants arguments have been fully considered, but are not found persuasive for the following reasons. Applicants have amended the claims to be drawn to the genus of any DNA that encodes a mutant LysE protein of a coryneform bacteria in which the glycine residue at position 56 is replaced with another amino acid residue, and not more than 10 amino acid residues at positions other than the 56th residues are varied, wherein said mutant impart resistance to S-(2aminoethyl-cysteine) in a methylotroph.

Applicants argue that one of ordinary skill in the art would be enabled to make and use the invention as claimed in light of the specification and knowledge in the art concerning the LysE protein and provides sequence alignments in Appendix A to support this argument. However, the issue in the rejection is whether the 10 amino acid residues other than the 56th residues that are substituted, deleted or inserted will in fact retain the function ascribed to the protein. In addition, the claims recite the open language of "comprising". Therefore, the issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Art Unit: 1656

The alignments provided by applicant exemplify that the glycine at position 56 is conserved (see page 6 of the response, line 7), however, there is no indicia in the claims as to what residues the "not more than 10 amino acids modification" will comprise, nor any indicia as to whether the sequence can tolerate any of the 20 naturally occurring amino acids or any non-naturally occurring amino acid substitution or insertion into the claimed SEQ ID NO:2. The claims are not limited to only the naturally occurring amino acids and the open language comprising does not limit additions to said sequence elsewhere in the sequence. Further, there are no indicia as to whether deletion of 10 residues in the sequence anywhere in the sequence other than at position 56 will retain function. Therefore, the alignments provided by Applicants do not rectify the issues at hand. Thus, the instant claims are not enabled for the full scope of the claims.

## **NEW ISSUES**

### ***Claim Objection***

9. Claim 6 is objected to because of the following informalities:

Claim 6 is objected to because the following appears, "claim2" which should be "claim 2". Proper spacing is required.

Correction of the above is required.

### ***Conclusion***

10. No claims are allowable.


Art Unit: 1656

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957.

The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS 

Patent Examiner

10/10/05



**KATHLEEN M. KERR, PH.D.  
SUPERVISORY PATENT EXAMINER**